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CHICAGO, IL 60690				
EXAMINER				
LACLAIR, DARCY D				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/599,071

Applicant(s)

ITO ET AL.

Examiner

Darcy D. LaClair

Art Unit

1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/88)
Paper No(s)/Mail Date 9/19/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. **Claims 9-11** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9-11 recite the limitation "stimuli-responsive polymer hydrogel" in Claim

1. There is insufficient antecedent basis for this limitation in the claim. Specifically, there is no Claim 1. For the purposes of examination, these product claims will be treated as though they depend from independent Claim 8, which is the independent product claim describing a stimuli-responsive hydrogel polymer.

Claim 10 requires that the water-insoluble polymer has a glass transition temperature lower than a working temperature of the hydrogel,...polymer has a rubbery characteristic at the working temperature. It is not understood what the "working temperature" is, with regard to the claims. In the specification, applicant indicates that when the stimuli-responsive polymer is used at room temperature, the water-insoluble temperature preferably has a glass transition temperature lower than 20°C. (see p. 26, par 1) However in the inventive examples, the glass transition temperature of the water-insoluble polymer is 105°C (see p. 28, par 6), 78°C (see p. 30 par 1), and -35°C (see p. 31 par 1), respectively. While there appears to be support for a working

temperature around the boiling point of water, at room temperature, and below freezing, it is not understood which of these working temperatures is required by the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 8-9, 11, and 14** are rejected under 35 U.S.C. 102(b) as being anticipated by **Wu et al. (US 2002/0001571)**.

With regard to Claim 8, Wu teaches a composite polymeric system for enhanced stimuli-responsiveness having a stimuli-responsive polymer which responds to various stimuli and a second polymer incorporated therein which is relatively insensitive to stimuli, which can be applied to systems comprising a hydrogel and non-swallowable hydrophobic polymer. (See abstract) The second polymer acts as a matrix for the stimuli-responsive polymer (see par [0012]) and a hydrophilic and hydrophobic polymer would be immiscible, and therefore a phase separation structure would be obtained. A swallowable polymer is consistent with a hydrogel polymer capable of gelating.

With regard to Claim 9, Wu does not disclose a crosslinking process, but does disclose that existing systems are prepared by chemical reactions such as cross-linking, and explains why the disclosed system overcomes that disadvantage. (See par [0007])

This indicates that Wu is not using a water-insoluble polymer having a cross-linking point.

With regard to Claim 11, the invention provides polymer particles which respond to stimuli such as pH change. (see abstract) Wu discloses an example which releases drug solution by changing volume with temperature. (See par [0006]) Wu teaches that the preferred stimuli-responsive polymer is swellable (or volume changing) (see par [0013]). Wu exemplifies a particle diameter change with temperature (see par [0052], Fig 1), and a pH responsive permeation change (see par [0065]). This suggests that a pH responsive diameter (volume) change should be expected. Furthermore, Wu exemplifies poly(N-isopropylacrylamide-co-methacrylic acid) as the responsive polymer. This has intramolecular acidic functional groups, and would therefore exhibit pH-responsive behavior. (See applicant's p. 24 par 6) Case law holds that a material and its properties are inseparable. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)

With regard to Claim 14, while there is no disclosure that the stimuli-responsive composite polymeric system capable of application to other systems comprising a swellable hydrogel and a nonswellable hydrophobic polymer is an actuator, as presently claimed, applicant's attention is drawn to MPEP 2111.02 which states that "if the body of a claim fully and intrinsically sets forth all the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction".

Further, MPEP 2111.02 states that statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the purpose or intended use results in a structural difference between the claimed invention and the prior art. Only if such structural difference exists, does the recitation serve to limit the claim. If the prior art structure is capable of performing the intended use, then it meets the claim.

It is the examiner's position that the preamble does not state any distinct definition of any of the claimed invention's limitations and further that the purpose or intended use, i.e. an actuator, recited in the present claims does not result in a structural difference between the presently claimed invention and the prior art stimuli-responsive polymeric system and further that the prior art structure which is a stimuli-responsive polymer hydrogel is identical to that set forth in the present claims is capable of performing the recited purpose or intended use. Since the particular limitations involved, with respect to the hydrogel are the same as the ones described in claim 1, attention is drawn to the discussion of **Claim 8**, above.

3. **Claims 8-9, 11, and 14** are rejected under 35 U.S.C. 102(b) as being anticipated by **Cleary et al. (US 2003/0170308)**.

With regard to Claim 8 and 11, Cleary teaches a hydrogel composition having a continuous hydrophobic or hydrophilic phase and a discontinuous hydrophilic phase. (See abstract) The continuous hydrophobic polymer is insoluble in water, (see par [0012]) as is continuous hydrophilic phase, (see par [0013]) therefore the requirement

for a water-insoluble phase separation structure is met by either of these embodiments. Cleary also discloses an alternate embodiment where there is a discontinuous hydrophobic phase and a continuous hydrophilic phase. (See par [0079]) The hydrophilic phase can be composed of compounds incorporating acrylic acid salts, acrylamide, and other components, (see par [0068]) cellulose esters such as cellulose acetate (see par [0091]) and acrylate polymers (see par [0094]). These are water swellable hydrophilic polymers, which is consistent with a hydrogel capable of gelating as a result of absorbin and swelling with water. Cleary teaches that acrylate containing compositions can generally provide swelling in the range of about 400% to 1500% upon impersion of the hydrogel compositions in water or other aqueous liquid, and the ratio of acrylate to hydrophilic polymer can be selected so the extent of swelling has a pH dependence. (See par [0116])

With regard to Claims 9, Cleary discloses that the hydrophobic phase comprises a hydrophobic polymer, an elastomeric plasticizer, and a tackifying resin. (See par [0052]-[0055]) The plasticizer is block copolymers of styrene, methyl styrene, vinyl toluene, and the like. (See par [0061]) The plasticizer is consistent with the water-insoluble polymer. In the exemplified compositions, the styrene plasticizer (not crosslinked) is the main constituent of the hydrophobic phase, along with a SBS copolymer (not crosslinked) and a hydrocarbon resin (not crosslinked). (See Example 1, par [0193]-[0198]) This is consistent with the water-insoluble polymer being a polymer without a cross-linking point.

With regard to Claim 14, while there is no disclosure that the hydrogel composition is an actuator, as presently claimed, applicant's attention is drawn to MPEP 2111.02 which states that "if the body of a claim fully and intrinsically sets forth all the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction". Further, MPEP 2111.02 states that statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the purpose or intended use results in a structural difference between the claimed invention and the prior art. Only if such structural difference exists, does the recitation serve to limit the claim. If the prior art structure is capable of performing the intended use, then it meets the claim.

It is the examiner's position that the preamble does not state any distinct definition of any of the claimed invention's limitations and further that the purpose or intended use, i.e. an actuator, recited in the present claims does not result in a structural difference between the presently claimed invention and the prior art hydrogel and further that the prior art structure which is a hydrogel composition is identical to that set forth in the present claims is capable of performing the recited purpose or intended use. Furthermore, Cleary recognizes that acrylate containing compositions can generally provide swelling in the range of about 400% to 1500% upon immersion of the hydrogel compositions in water or other aqueous liquid, and the ratio of acrylate to hydrophilic polymer can be selected so the extent of swelling has a pH dependence.

(See par [0116]) This provides the mechanics which would be necessary for an actuator device. Since the particular limitations involved, with respect to the hydrogel are the same as the ones described in claim 1, attention is drawn to the discussion of **Claim 8**, above.

4. **Claim 10** is rejected under 35 U.S.C. 102(b) as being anticipated by **Cleary et al. (US 2003/0170308)** with **evidence** provided by **Kraton Labels (2009)**.

The discussion of **Cleary**, above in **par 3**, is incorporated here by reference.

With regard to Claim 10, Cleary teaches a plasticizer which is block copolymers of styrene, methyl styrene, vinyl toluene, and the like. The plasticizer decreases the glass transition temperature of the hydrophobic polymer. (See par [0061]) In the exemplified compositions, the styrene-isoprene plasticizer, Kraton, (see par [0176]) is combined with a SBS copolymer (see par [0177]). (See Example 1, par [0193]-[0198]) Kraton teaches that the combination of a styrene-isoprene (Kraton D SIS) plasticizer with a styrene-butadiene-styrene (SBS) copolymer gives adhesives with extremely low glass transition temperatures which can be dispensed in chilled or deep freeze environments. (See Kraton Labels, End Use Products, par 2) Based on the combination of Kraton SIS copolymer and a SBS copolymer, it appears that the hydrophobic, water insoluble polymer portion of the composition would have a glass transition temperature which is well below room temperature, and therefore below expected working temperatures.

5. **Claims 8, 11 and 13-14** are rejected under 35 U.S.C. 102(b) as being anticipated by **Turner et al. (US 6,331,578)**.

With regard to Claim 8 and 11, Turner teaches that a preferred embodiment of the present invention is preparation of bicontinuous hydrophilic-hydrophobic IPN membranes having a uniform composition, where the hydrophobic component is the host network and the hydrophilic component is the guest network. The polymers are stimuli-responsive. (See col 9 line 12-20) This is consistent with a stimuli-responsive polymer, and the hydrophobic polymers are by nature water insoluble. The host and guest networks detail a phase separation. Turner teaches a hydrogel component which is a stimuli responsive polyelectrolyte electrogel which changes gel volume as a function of pH. (See col 15 line 47-50)

With regard to Claim 13, Turner teaches that the reaction mixture, comprising the hydrophobic polymer network, hydrophilic second component, as well as crosslinking agent and initiator of the hydrophilic component is combined. (See col 13 line 16-20) Polymerization and crosslinking reactions are initiated by heat or UV. (See col 14 line 34-35) Turner teaches that once formed, the network is immersed in water to wash away all of the unreacted components. (See col 14 line 50-51) Turner further teaches that washing in distilled water will remove unreacted components and swell the resulting network, (see col 18 line 10-11) which is consistent with yielding a hydrogel.

With regard to Claim 14, while there is no disclosure that the interpenetrating polymer network having a stimuli-responsive hydrogel component is an actuator, as presently claimed, applicant's attention is drawn to MPEP 2111.02 which states that "if

the body of a claim fully and intrinsically sets forth all the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction". Further, MPEP 2111.02 states that statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the purpose or intended use results in a structural difference between the claimed invention and the prior art. Only if such structural difference exists, does the recitation serve to limit the claim. If the prior art structure is capable of performing the intended use, then it meets the claim.

It is the examiner's position that the preamble does not state any distinct definition of any of the claimed invention's limitations and further that the purpose or intended use, i.e. an actuator, recited in the present claims does not result in a structural difference between the presently claimed invention and the prior art hydrogel and further that the prior art structure which is a hydrogel composition is identical to that set forth in the present claims is capable of performing the recited purpose or intended use. Furthermore, Turner recognizes the IPN material, used as a stimuli-responsive material, must expand and retract to accommodate the volume changes of the hydrophilic component. (See col 10 line 57-60) This describes the expected behavior of an actuator. Since the particular limitations involved, with respect to the hydrogel are the same as the ones described in claim 1, attention is drawn to the discussion of **Claim 8**, above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 9-10 and 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Turner et al. (US 6,331,578)**.

The discussion of **Turner**, above in **par 5**, is incorporated here by reference.

With regard to Claim 9, Turner teaches that semi-IPNs can be prepared in which one or more of the polymer components remains linear. (See col 9 line 30-31) The linear component is consistent with a polymer having no crosslinking point. The hydrophobic polymer is not water-soluble by virtue of being hydrophobic. While Turner does not explicitly disclose which of the components remains linear, it would be obvious to one of ordinary skill in the art that the hydrophobic polymer, one of two possible choices, would be the component which is not crosslinked. Furthermore, the functionality of a hydrophilic hydrogel polymer is based in the crosslinked structure which allows the polymer to expand to many times the dry size. Therefore it would be obvious to one of ordinary skill in the art, when working with a hydrogel system, to employ the hydrophobic component as the linear component.

With regard to Claim 10, Turner teaches that the host polymer network should be an elastomeric polymer network because the when the material is used as a stimuli-

responsible material, the host polymer network must expand and retract to accommodate the volume changes in the hydrophilic component. (See col 10 line 56-60) It is preferred that the hydrophobic polymer be elastomeric. (See col 11 line 11-12) This is consistent with a polymer having a rubbery characteristic. It would be obvious to one of ordinary skill in the art to select a hydrophilic polymer having a low glass transition temperature, such that the elastomeric/rubbery characteristic be maintained at the working temperature, rather than undergoing glass transition and becoming crystalline and brittle, which would be contrary to Turner's teaching for an elastomeric polymer.

With regard to Claim 12, Turner teaches that the reaction mixture, comprising the hydrophobic polymer network, hydrophilic second component, as well as crosslinking agent and initiator of the hydrophilic component is combined. (See col 13 line 16-20) Polymerization and crosslinking reactions are initiated by heat or UV. (See col 14 line 34-35) Turner exemplifies the production of a network in which the host polymer network was dried under a vacuum of 25 mm Hg for 6 hours, and then placed in an oven having a temperature of 55°C. (see col 16 line 29-33) The prepared polymer network was placed in cyclohexane to remove unreacted components (see col 16 line 37), and subsequently dried to constant mass (see col 17 line 30). It would be obvious to one of ordinary skill in the art to use either of the previous drying methods to dry or remove solvents from a prepared polymer gel. Turner further teaches washing a prepared network in distilled water will remove unreacted components and swell the resulting network, (see col 18 line 10-11) which is consistent with yielding a hydrogel.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darcy D. LaClair whose telephone number is (571)270-5462. The examiner can normally be reached on Monday-Thursday 7:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on 571-272-1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Darcy D. LaClair
Examiner
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/DDL/

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